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10/502,431	07/22/2004	Curtis C. Harris	4239-64141-02	3960

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EXAMINER
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HALVORSON, MARK

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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06/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/502,431

Applicant(s)

HARRIS ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15, 18-38 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) 3-11, 13, 15, 18-38, 40-42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 44 is/are allowed.
- 6) ☒ Claim(s) 1, 43, 45-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-11, 13, 15, 18-38, 40-48 are pending.

Claim 3-11, 13, 15, 18-38, 40-42 have been withdrawn.

Claims 1, 2 43-48 are currently under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 43 was inadvertently withdrawn in the Office Action of January 17, 2007. In this regard, Claim 43 is under examination in the present Office Action.

#### ***35 USC § 112 1<sup>st</sup> paragraph rejection maintained***

The rejection of claim 1 for failing to comply with the written description requirement is maintained.

Applicants argue that the specification discloses the p28ING5 amino acid sequence (SEQ ID NO: 2), as well as portions of SEQ ID NO: 2, set forth as amino acids 1- 13 and 222-240. Second, the specification clearly discloses that variants of SEQ ID NO: 2 may be defined in terms of their sequence identity. The specification further describes that mutation, substitution, or deletion of residues within conserved regions, such as a p28ING5 nuclear localization signal (corresponding to residues 222-240 of SEQ ID NO: 2) can alter tumor suppressor activity. In addition, Figure 12 discloses an alignment of five ING family protein sequences and identifies residues corresponding to consensus positions (darkened boxes). Thus, Applicants submit that the pending claims are sufficiently described by the specification and the scope of the claimed genus is not unreasonably overbroad.

Applicants further argue that a person of ordinary skill could easily envision sequence variants of a p28ING5 tumor suppressor protein, based on the teachings of the specification and the provision of the sequence itself.

Applicant's arguments have been fully considered but they are not persuasive. Applicants have not specifically pointed out which mutations, substitutions, or deletions are critical for the function of the p28ING5 tumor suppressor protein as contemplated in the specification. Applicants have only disclosed one species out of the claimed genus of p28ING5 tumor suppressor proteins and have not provided sufficiently detailed functional language in the claims to be able to couple the function with a known or disclosed correlation between function and structure. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that Applicants were not in possession of the claimed genus.

***35 USC § 102(e) rejections maintained***

The rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by Azimzai et al is maintained.

Applicants argue that Azimzai et al is not prior art in view of the submitted Declaration under 37 C.F.R. § 1.131.

The Declaration filed on April 17, 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Azimzai et al reference. Applicant swear behind Azimzai et al. Applicant states SEQ ID NO: 2 protein had been invented before the publication date of Azimzai et al. However, the product disclosed in Azimzai et al., and SEQ ID NO: 2 applicant invented first, are two different products. Therefore, it is considered applicant has not invented first.

One of the requirements for a Declaration under 37 C.F.R. § 1.131 is that:

The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of invention in this country or in a NAFTA or WTO member country (MPEP § 715.07(c)), at least the conception being at a date prior to the effective date of the reference.

The evidence submitted is insufficient to establish applicant's alleged actual reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Azimzai et al reference.

Applicants Declaration under 37 C.F.R. § 1.131 does not specifically point out where the invention was made and thus the Declaration is defective.

## **NEW REJECTIONS:**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43, 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of purified p28ING5 tumor suppressor proteins having a sequence comprising amino acid residues 1-13 and 222-240 of SEQ ID NO: 2, or a sequence having one or more conservative substitutions thereof, wherein the sequence has at least 90%, 95% or 98% sequence identity over the entire length of SEQ ID NO:2.

The specification discloses only one purified p28ING5 tumor suppressor protein, the protein of SEQ ID NO:2.

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name,

of the claimed subject matter sufficient to distinguish it from other materials.” Id. At 1567, 43 USPQ2d at 1405. The court concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” Id.

The Federal Circuit has recently clarified that a molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of the genus of p28ING5 tumor suppressor proteins, per Lilly by structurally describing a representative number of p28ING5 tumor suppressor proteins that function as claimed or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the genus of p28ING5 tumor suppressor proteins in a manner that satisfies either the Lilly or Enzo standards. There are insufficient structural features common to all members of the genus of polypeptide antagonists. The genus of p28ING5 tumor suppressor proteins encompasses any polypeptide having 85%, 90%, 95% or 98% sequence identity to SEQ ID NO:2. Even a genus of peptides consisting of peptides with 2% difference in sequence identity to SEQ ID NO:2 would describe a large number of p28ING5 tumor suppressor proteins. Thus, the claims encompass a multitude of p28ING5 tumor suppressor proteins, only one of

which is identified in the instant specification. One species of p28ING5 tumor suppressor protein, does not sufficiently describe the genus of p28ING5 tumor suppressor proteins and does not meet the standard set forth in Lilly.

The instant specification may also provide an adequate written description of the genus of p28ING5 tumor suppressor proteins if the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. The specification discloses only one species of p28ING5 tumor suppressor protein. Thus, the specification does not describe sufficient structural characteristics that correlate with the ability of the genus of p28ING5 tumor suppressor proteins to function as contemplated by the specification and for the reasons set forth above do not meet the standards set forth by Enzo.

Thus, the specification does not provide an adequate written description of the genus of genus of p28ING5 tumor suppressor proteins of claims 43, 45-48 that is required to practice the claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 45-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Azimzai et al (U.S. Patent Application Publication, published Jun 15, 2006, filing date Aug 8, 2002, priority date Sep 7, 2001).

The claims are drawn to a purified p28ING5 tumor suppressor protein having a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2, or a sequence having one or more conservative substitutions thereof, wherein the sequence has at least 90%, 95% or 98% sequence identity over the entire length of SEQ ID NO:2.

Azimzai et al disclose a polypeptide having an amino acid sequence of SEQ ID NO:16 that is identical except for a proline at position 170 instead of a serine. Thus, Azimzai et al's peptide comprises amino acid residues 1-13 and 222-240 of SEQ ID NO: 2, wherein the sequence has at least 98% sequence identity over the entire length of SEQ ID NO:2, of the instant application.

### ***Summary***

No claims allowed.

Claims 2 and 44 appear to be free of the prior art as the closest prior art is Azimzai et al that discloses a protein identical to SEQ ID NO:2 of the present invention except for amino acid proline at position 170 instead of serine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic



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Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson

Patent Examiner

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/Misook Yu/

Primary Examiner, Art Unit 1642